

## **REMARKS**

Claims 1, 22, 23, 25 to 28, 31, 33, 34, 36 and 38 to 63 are currently pending on entry of the amendments above. Claims 2 to 21, 24, 29, 30, 32, 35 and 37 have been cancelled without prejudice or disclaimer and Applicants reserve the right to pursue the subject matter of these claims in related applications.

Original claim 57 has been amended so as to recite “[t]he method of claim 39 wherein said toxin.” Support for this amendment is found in the specification and claim 39 as originally filed. Accordingly, no new matter has been introduced on entry of this amendment.

## **Restriction Requirement**

The Examiner has required an election under 35 U.S.C. § 121 of one of the following groups:

- Group 1. Claims 1-21, are drawn to a nucleic acid molecule encoding a protein of amino acid sequence of set forth in SEQ ID NO:2, a vector, a host cell, and a method for making the protein, classified in Class 435, subclass 69.1.
- Group 2. Claim 22, is drawn to a polypeptide of amino acid sequence of set forth in SEQ ID NO:2, classified in Class 530, subclass 350.
- Group 3. Claims 23-24 are drawn to an antibody to a polypeptide of amino acid sequence of set forth in SEQ ID NO:2, classified in Class 530, subclass 387.9.
- Group 4. Claims 25, 29-30, 35, 37, are drawn to a method of treating an immunodeficiency disease comprising administering the polypeptide of amino acid sequence set forth in SEQ ID NO:2, classified in Class 514, subclass 2.
- Group 5. Claims 26, 31, 33, 34, 36, 38, 39, 40-41, 42-63, are drawn to a method of treating an immunodeficiency disease comprising administering an antibody to the polypeptide of

amino acid sequence set forth in SEQ ID NO:2, classified in Class 514, subclass 130.1.

Group 6. Claim 27, 30, is drawn to a method of diagnosing an autoimmune disease using a polypeptide of SEQ ID NO:2, classified in Class 435, subclass 7.1.

Group 7. Claim 28, 32, is drawn to a method of diagnosing an autoimmune disease using an antibody to a polypeptide of SEQ ID NO:2, classified in Class 435, subclass 7.1.

*See*, Paper No. 5, page 2. The Examiner contends that the inventions are distinct, each from the other.

Preliminarily, Applicants point out that claim 30 has been identified as belonging to two groups as defined by the Examiner. *See*, Paper No. 1 at page 2. Applicants believe this to be in error and based upon the description contained in Paper No. 1, believe that this claim properly belongs to the subject matter of group 6 as defined by the Examiner.

In order to be fully responsive, Applicants provisionally elect, *with traverse*, the subject matter of group 5 as represented by originally filed claims 26, 31, 33, 34, 36 and 38 to 63, and drawn to a method of treatment using an antibody to the polypeptide of SEQ ID NO:2, for further prosecution. Applicants reserve the right to file one or more divisional applications directed to non-elected inventions should the restriction requirement be made final. Additionally, should the present restriction requirement be made final, Applicants retain the right to petition from the restriction requirement under 37 C.F.R. § 1.144.

Applicants point out that claims 2 to 21, 24, 29, 30, 32, 35 and 37 have been canceled and that no new claims have been added.

Applicants respectfully traverse and request the withdrawal of the Restriction Requirement. As a threshold matter, Applicants point out that MPEP § 803 lists the criteria for a proper restriction requirement:

Under the statute an application may properly be required to be restricted to one of two or more claimed inventions only if they are able to support separate patents and they are either independent (MPEP § 806.04 – § 806.04(i)) or distinct (MPEP § 806.05 – § 806.05(i)).

If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions.

Thus, even assuming, *arguendo*, that the groups listed by the Examiner represented distinct or independent inventions, restriction remains improper unless it can be shown that the search and examination of both groups would entail a “serious burden.” *See* M.P.E.P. § 803.

In the present situation, no such showing has been made. Although the Examiner has argued that groups 1 through 7 are separately classified, Applicants nonetheless submit that a search of the claims of group 1 would also provide useful information for the claims of groups 2 and 3, while a search of the claims of group 2 would provide useful information for the claims of groups 1 and 3, and search of the claims of group 3 would provide useful information for the claims of groups 1 and 2. Indeed, since groups 1 and 2 are directed to polynucleotides and the amino acid sequences they encode, a search of both of these groups would largely, if not entirely, overlap. Furthermore, since groups 2 and 3 are directed to amino acid sequences and antibodies they bind, a search of both of these groups would largely, if not entirely, overlap. Thus, since the searches for sequence of group 1, polypeptide of group 2, antibodies of group 3 would overlap, the search and

examination of all these groups would not entail a serious burden. Furthermore, Applicants submit that a search of the claims of group 4 would also provide useful information for the claims of groups 5, 6 and 7, while a search of the claims of group 5 would provide useful information for the claims of groups 4, 6 and 7, a search of the claims of group 6 would provide useful information for the claims of groups 4, 5 and 7, and search of the claims of group 7 would provide useful information for the claims of groups 4, 5 and 6. Since groups 4 and 5 are directed to methods of treatment using polypeptides and antibodies that bind them, a search of both of these groups would largely, if not entirely, overlap. Furthermore, since groups 6 and 7 are directed to methods of diagnosis using polypeptides and antibodies that bind them, a search of both of these groups would largely, if not entirely, overlap. Further still, since groups 6 and 7 are directed to methods of diagnosis using polypeptides and antibodies that bind them, and groups 4 and 5 are directed to methods of treatment using those same polypeptides and those same antibodies that bind them, a search of both of these pairs of groups would largely, if not entirely, overlap. Thus, since the searches for treatment methods of groups 4 and 5, and the diagnostic methods of groups 6 and 7 would overlap, the search and examination of all these groups would not entail a serious burden.

For example, in many if not most publications disclosing the use of a polypeptide in treating or ameliorating a disease, a polynucleotide is described which encodes that polypeptide. Furthermore, in many if not most publications disclosing altered expression of a polypeptide in a disease, a suggestion is made that regulation of the function and/or expression of that polypeptide may be useful in treating and/or ameliorating that disease. Accordingly, since the searches for diseases overlap, and the searches for polynucleotides

and polypeptides overlap, the search and examination of all groups of the instant application would not entail a serious burden.

Accordingly, in view of M.P.E.P. § 803, the claims of all groups 1-7 should be searched and examined in the present application. Applicants therefore respectfully request that the restriction requirement under 35 U.S.C. § 121 be reconsidered and withdrawn, and that the instant claims be examined in one application.

Applicants respectfully request that the above-made amendments and remarks be entered and made of record in the file history of the instant application.

**Conclusion**

In view of the foregoing remarks, applicants believe that this application is now in condition for substantive examination. The Examiner is invited to call the undersigned at the phone number provided below if any further action by applicant would expedite the examination of this application.

Finally, if there are any fees due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 08-3425. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,



---

Kenley K. Hoover (Reg. No. 40,302)  
Attorney for Applicants

**Human Genome Sciences, Inc.**  
9410 Key West Avenue  
Rockville, MD 20850  
(301) 610-5771 (phone)

Enclosures  
KKH/BM/lcc